EXHIBIT 3

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION) MDL No. 2875

VIDEOTAPED DEPOSITION OF:

EDWARD H. KAPLAN, M.D.

WEDNESDAY, JANUARY 19, 2022

9:14 a.m. Central Standard Time

TRANSCRIPT of the stenographic notes of the proceedings in the above-entitled matter as taken by and before KELLY A. BRICHETTO, a Certified Court Reporter of the State of Illinois, held at 77 West Wacker Drive, Suite 3100, Chicago, Illinois, on Wednesday, January 19, 2022, commencing at approximately 9:14 a.m. pursuant to notice.

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ALSO PRESENT:
BEN PELTA-HELLER, Videographer
SCOTT ZIARKO, Videographer

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EXHIBIT CUSTODY
COURT REPORTER

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THE VIDEOGRAPHER: Good morning. We are now on the record. My name is Scott Ziarko. I'm the videographer representing Veritext Legal Solutions.

Today's date is January 19th, 2022. The time is approximately 9:14 a.m. This deposition is being held at 77 West Wacker Drive in Chicago, Illinois as well as by Zoom meetings in the matter of In Re: Valsartan, Losartan, et al. The name of the witness is Edward H. Kaplan, M.D.

Our court reporter is Kelly Brichetto who is also with Veritext Legal Solutions.

All counsel will be noted in the written record.

Would the court reporter please swear in the witness.

(Witness sworn.)

You may begin.

MR. KERNER: Before we get started, Scott, can we move the video camera just a touch to get the laptops out of the screen since I can't get any closer?

THE VIDEOGRAPHER: There you go.

MR. KERNER: Great.

THE WITNESS: And I have to look at myself.

MS. GEMAN: I'm sorry. My pen literally just

died. Using the word literally correctly. Is there one back here?

MR. KERNER: We're off to an auspicious beginning.

MS. GEMAN: Indeed. I have others in my room. I can go get it.

MR. KERNER: You need a pen?

MS. GEMAN: I need a pen.

MR. KERNER: Do we need this on video?

THE VIDEOGRAPHER: Want to go off the record?

MR. KERNER: Yeah, go off the record.

THE VIDEOGRAPHER: The time is 9:15. We're off the record.

(Discussion had off the record.)

The time is 9:16 a.m. We're back on the record. This is media two.

Will the court reporter please swear in the witness.

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(Witness sworn.)
WHEREUPON:
EDWARD H. KAPLAN, M.D.,
called as a witness herein, having been first duly sworn, was examined and testified as follows:
DIRECT EXAMINATION
BY MR. KERNER:
Q. Good morning, Dr. Kaplan.
A. Good morning.
Q. My name is Glenn Kerner. We met a new minutes ago. I am an attorney representing Teva Pharmaceuticals in this litigation. I'm here with Greenberg Traurig. My partner Nilda Isidro is here as well, and I'm going to be asking you a bunch of questions this morning, possibly into this afternoon as well about your report and the litigation and your opinions in the litigation.
Have you ever had your deposition taken before?
A. Yes.
Q. How many times?
A. Three or four times, maybe more. Six times.
Q. Okay. So then you know how it goes. You're under oath, so you have sworn to tell the truth.

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The way this works obviously is I'm going to ask you questions. You're going to answer my questions. It will be recorded by both the videographer and the stenographer here, so there will be a booklet that has -- there'll be a transcript that will have all of your testimony in it. Do you understand that?
A. I do. Since this is video and I've not been videoed, when I nod my head, that works because in the past --
Q. It doesn't. No, you still need to answer verbally so the stenographer can get it.
A. Got it. Okay.
Q. But thank you for asking.
If I ask a question and you're not quite sure what I mean, please tell me.
A. Okay.
Q. Because if you answer my question, I'm going to assume that you understood it, and then it will go into the record. We don't want to have any misunderstandings. Okay?
A. Okay.
Q. Also, I do have a habit sometimes of speaking quickly, so I want to warn you in advance of that, so let's try not to talk over each other, and I will try as

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well.
A. Okay.
Q. In the prior depositions that you've taken or that you've been deposed, can you tell me when the first one was, approximately?
A. Twenty years ago.
Q. What kind of case was it?
A. Malpractice.
Q. Medical malpractice?
A. Medical malpractice.
Q. And were you a party in that case or were you a witness?
A. A witness.
Q. Were you an expert witness in that case?
A. I believe I was an expert witness in that case.
Q. Were you paid to testify?
A. Yes.
Q. And can you give me some of the details of that case?
A. I can't remember exactly because it's been more than ten years since I've done any, but if it's the one I'm thinking of then, it was -- it was a woman with breast cancer, and I was asked to be an expert for the

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plaintiff.
Q. And what was the claim in that case?
A. The claim was -- was that she was misdiagnosed. Late diagnosis caused her -- her disease to progress and ultimately caused her demise.
Q. You say that was about 20 years ago you think?
A. I believe it was about 20 years ago.
Q. Where was that case?
A. It was in -- it was on the west -- it was on the north -- in the northwestern United States.
Q. Oregon, Washington, something like that?
A. One of those places.
Q. You don't remember though?
A. I will later on I'm sure.
Q. Okay. Well, if you remember, please let us know.
A. Okay.
Q. Do you remember the name of the attorney that retained you?
A. I do not.
Q. Do you remember the name of the firm?
A. It was an independent person. He was not generally a malpractice attorney. That much I remember.

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I don't remember his name.
Q. How did he find you?
A. Through a radiologist friend of mine who was asked -- who had done a lot of this and was asked to find a medical oncologist that could review the case and opine.
Q. And when you say "review the case," did you testify in that case as well?
A. Yes.
Q. At deposition, as you said you did?
A. I testified in court.
Q. And at deposition, both?
A. And in deposition.
Q. And what was the result of that case?
A. I believe that the case was dropped. I don't think it -- it went to court, but I don't think it -- it progressed after the time I was in the courtroom.
Q. When you say it was dropped, do you know what you mean by that or is that just a layman's term?
A. Honestly I --
MS. GEMAN: I just want to caution you both. Please let him finish his question --
THE WITNESS: Oh.
MS. GEMAN: -- and likewise.

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MR. KERNER: I warned you.
MS. GEMAN: Right, but there was --
MR. KERNER: Almost.
MS. GEMAN: No, there was one cutoff of the answer. Thank you, both.
THE WITNESS: Could you repeat the question?
BY MR. KERNER:
Q. Sure. You said the case was dropped. Do you know what you meant by that?
A. So I can't remember if that case was -- was withdrawn or if it was that they found in favor of the defendant. I don't -- and it came to conclusion, but after my testimony I didn't have any more interaction. I think they had -- the attorney and the client had some issues, and I think they may have got other counsel. I can't remember all the details.
Q. Okay. Do you remember the name of the case?
A. No, I do not.
Q. Do you remember the name of the defendant --
A. I do not.
Q. -- the name of the doctor?
A. I do not.
Q. Was it a doctor? Sorry.
A. It was -- it was a doctor, a group of doctors

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and a medical center I believe or a hospital.
Q. Do you know what hospital that was or what medical center it was?
A. I don't remember any of the details.
Q. Okay. Do you remember anything else about that particular case?
A. No, I really don't.
Q. Okay. When was the next time you had your deposition taken?
A. I really can't remember the times of these. I know I have had nothing within the last ten years. That's really what I can tell you.
Q. Okay. I believe you testified that your deposition has been taken three or four times. So you told us about one.
A. Right.
Q. Can you tell us about another one?
MS. GEMAN: Just objection to the extent it misstates testimony.
MR. KERNER: I'm sorry. I didn't hear it.
MS. GEMAN: Maybe I should take this off. Sorry.
Objection to the extent it misstates testimony.

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BY THE WITNESS:
A. I had a deposition taken on a patient that I was caring for. In fact, this was probably even before that case, so it may have been more like 25 years ago. And it was a young woman who had gastroesophageal cancer or stomach cancer. I can't remember exactly. She was my patient for a brief time. It was towards the end of her -- of her life, and I was asked -- I was deposed to -- as to her condition and to the -- and to the issues surrounding her diagnosis. I wasn't opining as to -- as to causation or -- or fault. I was just deposed as her treating doctor.
BY MR. KERNER:
Q. Were you a party in that case?
A. No.
Q. You weren't a defendant in that case?
A. No, I was not.
Q. So you were just a fact witness?
A. I was a -- I was a treating physician at the time of her death.
Q. Okay. Do you remember where that case was pending?
A. It was in my office in Skokie.

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Q. Do you remember the name of the attorney who took your deposition?
A. I do not.
Q. Do you remember the name of the doctor who was the -- was the doctor -- was there a doctor as the defendant in the case?
A. There probably was, but I wasn't -- I wasn't really asked to look at any of that. It just was my own records and my own treatment of the patient.
Q. Okay. And again just to be clear, you don't remember the name of either party or any of the parties in that case?
A. I do not.
Q. Any other depositions that you've taken or you've had rather?
A. I've done other depositions. I was deposed as an expert reviewing a patient -- it wasn't a -- he became a patient but it was a -- a person who was claiming exposure to toxins in the workplace, and his attorney wanted me to review that and to opine as to whether any of the chemicals that he was exposed to could have been related to his ultimate development of cancer.
Q. What kind of cancer did this person have?
A. I believe it was a soft tissue sarcoma.

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Q. So he was the plaintiff in that case?
A. He was the -- he was the plaintiff, correct.
Q. And his attorney asked you to review the medical records?
A. To review the -- to review the medical records but also to review the -- the various agents that he was exposed to and see if I could find any -- any specific link or causation for his ultimate cancer.
Q. And were you able to?
A. I was not able to find anything specifically linked.
Q. Do you recall what agents you looked at?
A. I just recall that there were a lot of -- of -- of cleaning agents. He was involved in -- in a factory that used a lot of solvents that were for -- for sterilization and cleaning, and I know I reviewed a lot of -- a lot of literature about those agents, and there was not any specific -- they were all -- they were all pretty much doing all the precautionary things that they needed to do in the work -- in the workforce.
Q. Do you remember what any of the agents were?
A. I really don't.
Q. Do you remember any of the classifications of any of those agents?

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A. Just that there were some -- some benzene-type products that were -- there were some fairly toxic substances that are used commonly in -- in cleaning solutions in the workplace and at home, but I don't remember specifics.
Q. And I'm sorry if I asked you this already. Do you remember the name of any of the parties in that case?
A. I -- I do not.
Q. What about any of the attorneys that you dealt with?
A. I -- I don't offhand remember the names. If I need to look --
Q. Why do you say it like that?
A. Because I can't --
MS. GEMAN: Objection.
BY THE WITNESS:
A. I can't remember the names. If I knew that I was going to be asked for depositions from before ten years, I would have reviewed whatever I could find in my old records to -- to get names and dates and places.
BY MR. KERNER:
Q. Okay. And so is it your testimony that you have some old records either at home or in your office

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that you would have reviewed?
MS. GEMAN: Objection, misstates the testimony.
BY THE WITNESS:
A. It's -- could you repeat that, please.
BY MR. KERNER:
Q. Sure. Do I understand your testimony to be that you have old records that you didn't review from prior to ten years ago?
A. What I'm saying is I could very well have something like that laying around since I tend not to throw things away, but I haven't looked in certain closets in the house for many years, so I would have to go looking through those if -- if I was being asked or knew I was going to be asked about them.
Q. Okay. Any other occasions where your deposition was taken?
A. I can't recall any -- any specifics of any other depositions, but I know I've been in my office deposed before.
Q. And before this litigation -- you've been retained as an expert witness in this litigation; correct?
A. Correct.

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Q. For the Plaintiffs; correct?
A. Correct.
Q. Before this litigation how many times have you been retained as an expert witness?
A. Again, it's been awhile. The last -- last 15 years was doing nothing in this regard because I was taking care of my wife who suffered from breast cancer and then ultimately passed away from it, so I was kind of out of the picture, and this is the first I've done in a long time. But your question was how -- how many times was I an expert?
Q. Correct.
A. Aside from the case that I just mentioned to you, I've been an expert in malpractice cases. Mostly record review rather than -- rather than deposition. Only a couple times did it actually go to deposition.
Q. Can you ballpark or estimate for me how many times you've been retained as an expert witness either to review documents or testify, a number?
A. In my lifetime?
Q. Yeah.
A. Seven or eight times.
Q. And out of that seven or eight total times, how many times do you think it went to deposition?

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A. Three.
Q. Okay. In those seven or eight total times where you've been retained as an expert witness, how many times were you retained for the defendant -- by the defendant?
A. It was about 50/50 percent.
Q. And in the times that you were retained by the defendant, were those defendants physicians?
A. Yes.
Q. Were there any occasions where the defendant was not a physician, where you were retained by a defendant who was not a physician?
A. I don't believe so.
Q. And so those would have been malpractice cases?
A. Correct.
Q. And in the times that you were retained by the plaintiff or plaintiffs, putting aside this litigation, how many of those were medical malpractice cases?
A. All.
Q. All?
A. Um-hum. Yes.
Q. So is this the first time that you have been

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retained as an expert witness in a case that is not a medical malpractice case?
A. Yes.
Q. And so now you've given us all of the depositions that you can remember as you sit here; correct?
A. Correct.
Q. What's your current professional address?
A. 9 -- 9631 Gross Point Road, Skokie, Illinois, 60076.
Q. Is that an office or a hospital?
A. It's an office building.
Q. And you have a practice that's just you? What is there?
A. It's a private practice that includes myself, one employed physician and then nurses and physician assistant and staff.
Q. And is it an oncology practice?
A. Yes, hematology and oncology.
Q. Tell me what hematology is.
A. Hematology is the study of -- of blood-related disorders.
Q. So is the practice primarily involved with blood cancers?

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A. No.
Q. What type of cancers does this practice deal with? Strike that.
Hematology and oncology. So does the practice deal with more than just cancer?
A. Yes.
Q. Does it deal with blood disorders and cancers?
A. Correct.
Q. What kind of blood disorders does it deal with?
A. Well, aside from the malignant blood disorders such as lymphomas, leukemias there are --
Q. And those are cancers?
A. Those are cancers. So you want the non-cancers?
Q. Correct.
A. So that would be -- that would be anemia, problems with other blood issues such as low platelet count, thrombocytopenia, bone marrow disorders such as mild dysplastic syndrome, mild proliferative neoplasms, multiple myeloma or plasma self dysplasias which kind of is the broad term for -- for that class of illnesses. Many things called monoclonal gammopathy of uncertain

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significance or MGUS which is pre-cursor to multiple myeloma, problems with just low blood counts in general, sickle cell disease, hemophilia. Those conditions are taken care of by my associate.

Q. You anticipated my question. So those blood disorders are dealt with by your associate?

A. Correct.

Q. And what is his or her name?

A. Dr. Marlon Kleinman. Marlon like Brando. Kleinman like Kleinman.

Q. And are you the only oncologist in the practice?

A. He's also an oncologist.

Q. Okay. And in that practice, do you deal exclusively with cancers?

A. No. I also do some hematology. We cover for each other. I do have some patients with those conditions I mentioned.

Q. Okay. What kind of cancers do you deal with in that practice?

A. Pretty much any cancer that there is except mostly I do not take care of acute leukemia. My partner sometimes will. My associate sometimes will, but mostly I take care of everything else. The majority of what I

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do though is solid tumors which would include gastrointestinal malignancies, lung cancer, breast cancer, lymphomas, other -- other GI -- oh, I mentioned gastrointestinal cancers. That could be -- that could be anywhere from the esophagus to the stomach to the small bowel to the large bowel, pancreas, gallbladder, biliary tree cancers, liver cancers.

Q. Why don't you handle acute leukemia cases?

A. Most of the time I believe that that disease requires the facilities of a tertiary care center, and while we may see patients that are also being treated in one of those centers, the majority of the treatment is administered and followed at those centers.

Q. Are there any other cancers you'd put into that same category?

A. No.

Q. What's so unique about acute leukemia that requires that?

A. Acute leukemia requires oftentimes inpatient treatments with close monitoring. It could -- it could require bone marrow transplantation and -- and other procedures that we're just not equipped to handle in an -- an in outpatient clinic, outpatient office.

Q. So you refer them to another facility?

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A. Most of the time, yes.

Q. By the way, a couple of preliminary questions I should have asked at the beginning.

You're not taking any medication that affects your memory today?

A. I don't think so. No, I'm not taking any. I'm sorry.

Q. And you're capable of testifying fully and truthfully today?

A. I better be, yes.

Q. That's a yes?

A. I've already started. Yes. Yes.

Q. I am going to hand you what the court reporter first -- we'll have her mark as Exhibit 1, the Notice of Videotaped Deposition today.

(Exhibit No. 1 marked as requested.)

MR. KERNER: Rachel, are you looking at the same thing?

MS. GEMAN: Yes.

BY MR. KERNER:

Q. Dr. Kaplan, have you ever seen what's been marked as Exhibit 1 prior to right now?

A. Yes.

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Q. When was the first time you saw it?

A. I believe it was about three or four weeks ago.

Q. How did you come to see it?

A. It was given to me by the attorneys.

Q. Which attorney?

A. Rachel or one of her colleagues.

Q. You don't remember?

A. I don't -- I don't remember, no.

Q. And you see that it calls for your deposition right here today. So you're here pursuant to this Notice of Deposition; correct?

A. Correct.

Q. There's also a request for some documents here. Did you review that before today?

A. Yeah.

Q. On Monday we received some documents. Were the documents that you provided in response to these requests?

A. Yes.

Q. Any documents in these requests that you didn't provide?

A. Not that I know of, no.

Q. So everything in these requests you provided

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on Monday to us; correct?
MS. GEMAN: Objection to the extent it calls for a legal conclusion subject to the responses and objections.
MR. KERNER: Okay. Let me ask it a different way.
BY MR. KERNER:
Q. Is there anything in this set of requests, these 13 requests that you have not provided to us?
A. I -- I do not believe so.
Q. So I asked that as a double negative there. Have you provided everything that was requested in these 13 requests --
MS. GEMAN: Same objection.
BY MR. KERNER:
Q. -- that was in your -- that's in your possession?
A. Yes.
Q. And so request number 6 is for your complete and entire file for the case. You provided that?
A. Yes.
Q. So there's nothing that you have in connection with this case that you haven't provided; is that accurate?

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MS. GEMAN: Same objection.
BY THE WITNESS:
A. There -- there were preliminary drafts which I was told I did not need to -- to provide.
MS. GEMAN: And I'm just going to caution the witness not to disclose communications with counsel.
MR. KERNER: Right.
BY THE WITNESS:
A. And communication with counsel.
BY MR. KERNER:
Q. I don't want to know about your communications with your counsel. Although I believe counsel here is Plaintiffs' counsel, so you're actually not -- there's not an attorney/client relationship, but we don't need to get into that now.
And I'm not looking for your drafts.
A. I'm sorry?
Q. I'm not looking for your drafts today.
A. Okay.
Q. Is there anything else that you didn't provide that was requested --
A. No.
Q. -- in these 13 requests?
A. No, there isn't.

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THE WITNESS: Can I take a break for one second --
MR. KERNER: Yeah, of course.
THE WITNESS: -- just to ask a question?
MR. KERNER: Hang on. Hang on. Do you want to go off the record? Yeah.
THE VIDEOGRAPHER: The time is 9:41 a.m. This is the end of media two. We're off the record.
(Discussion had off the record.)
The time is 9:43 a.m. This is the beginning of media three. We're back on the record.
BY MR. KERNER:
Q. We all set?
A. Yes.
Q. Okay. Dr. Kaplan, how did you first become aware of this litigation?
A. I was approached by or I was -- I was contacted by Expert Institute which is a company that has my -- my credentials, my information and they asked me if I'd be interested in discussing and reviewing this case and introduced me to the -- to the legal team that was involved in it.
Q. Who did they introduce you to?

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A. To -- to the law firm that -- that I'm -- that I'm with right now.
Q. Rachel's law firm?
A. Rachel's law firm.
Q. Lieff Cabraser, does that sound familiar?
A. Yeah, that's one of the law firms.
Q. What were the other ones?
A. I don't have the names in front of me.
Q. What did they tell you that they wanted you to do?
A. They asked if I could review or -- or develop a monitoring program for patients that had been shown to be exposed to known carcinogens.
Q. How do you define known carcinogens?
A. Products that have been identified to increase risk of developing malignancies when someone's been exposed to them in certain levels.
Q. And you said the Expert Institute put you in contact with Lieff Cabraser?
A. Correct.
Q. How did they have your contact information?
A. I had responded to e-mail requests awhile ago for somebody who would be interested -- for people who would be interested in being expert witness and sent them

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my information, my curriculum vitae, so I was on their file. I don't remember how long ago I did it, but this was the first time I had been contacted by them.

Q. How long ago did Plaintiffs' lawyers contact you?

A. I believe it was October of 2021, September or October.

Q. Just a few months ago?

A. Correct. Actually, it may have been a little before. It may have been August.

Q. And they asked you to develop a monitoring program for patients exposed to known carcinogens. How did you respond?

MS. GEMAN: Objection to the extent it misstates the testimony.

BY MR. KERNER:

Q. If that's not what you said, please correct it, but I think that's what you said.

A. Could you repeat the question?

Q. How did you respond to Plaintiffs' request to retain you as an expert?

A. I agreed to review the information.

Q. What information did you agree to review?

A. The testimony of experts that discussed the

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risks associated with nitrosamine products from tainted Valsartan.

Q. Which specific expert's testimony did you review?

A. I have it in my --

Q. In your report?

A. -- report.

Q. So the experts' testimony that you reviewed are the experts that you've identified in your report?

A. Correct.

Q. Any others?

A. No.

Q. And in addition to reviewing their testimony, did you review anything else?

A. At that time?

Q. Yes.

A. No.

Q. In preparing your report, did you review anything else or just that testimony?

A. No. In preparing my report, I reviewed various articles and resources.

Q. And are those articles and resources attached to your report?

A. Yes, they are.

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MR. KERNER: Let's mark this next exhibit. I think this is 2; right?

(Exhibit No. 2 marked as requested.)

BY MR. KERNER:

Q. Doctor, we've marked as Exhibit -- well, we've just handed you Exhibit 2. Can you tell me what that is?

A. This is a copy of my curriculum vitae.

Q. And can you tell me if that's your most current CV?

A. I believe it is.

Q. And this was attached to your report?

A. Yes.

MR. KERNER: How do we want to handle exhibits with the Zoom? I realize we didn't do that for the Notice of Deposition. Do we want to get the CV up on the Zoom for folks that are remote?

MS. ISIDRO: Yes. That's in progress.

MR. KERNER: Great.

BY MR. KERNER:

Q. So, Doctor, let's go backwards. Let's start with your medical school. Where did you go and when did you graduate?

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A. I went to Loyola University Medical Center in Maywood, Illinois, and I graduated in 1982.

Q. Did you have a residency after that?

A. I had a residency -- internship and residency at Northwestern University in Chicago.

Q. What did you do after the internship and the residency?

A. I went on to a hematology/oncology fellowship at Northwestern University in Chicago.

Q. And the residency was in internal medicine; correct?

A. Correct.

Q. And the fellowship was you said at Northwestern --

A. Yes.

Q. -- in hematology and oncology?

That was according to your CV from 1983 to 1985?

A. The fellowship was 1985 to 1988.

Q. Ahh, okay. And so after the fellowship, when it concluded in 1988, what did you do next?

A. I joined the faculty at Rush University in Chicago.

Q. In what role?

A. As a medical -- as a hematology/oncology attending physician.
Q. Is that still your role there?
A. No. I was -- I was full-time there for five years and then went into private practice after that but maintained my -- my teaching role at Rush University and am still an Assistant Professor of Medicine at Rush University.
Q. And you've been an Assistant Professor of Medicine at Rush since 1988?
A. Correct.
Q. What do your responsibilities at Rush entail now?
A. My responsibilities at Rush would entail allowing residents and students to rotate through our office to acquire clinical experience. There's been teaching roles. There's been clinical clerkships, but I have had no responsibilities on the campus for a number of years.
Q. When you say "allow them to rotate," what do you mean by that?
A. Providing them a rotation, a clinical rotation in our -- in our -- in our practice for the -- for the residents or -- or fellows that wish to have a

community oncology experience.
Q. Do you supervise them?
A. Yes.
Q. Do you teach them?
A. Yes.
Q. What do you teach them?
A. Teach them clinical -- clinical oncology. For -- for ten years -- until 1995 I was assigned as the -- the Chairman of Oncology at NorthShore University -- at -- sorry -- at Rush NorthShore in Skokie. That was part of my role at Rush. After I left full-time faculty at Rush I maintained that role until the hospital was sold to NorthShore University.
Q. Okay. Now, in looking at your CV, there are a bunch of publications, and I see there's some patents as well and some abstracts and invited lectures and presentations. How many of these publications dealt with NDMA or NDEA?
A. None.
Q. How about Valsartan or any of the Valsartan drugs?
A. None.
Q. What about the abstracts?
A. None.

Q. And the invited lectures and presentations --
A. Concerning?
Q. -- any of them concerning NDMA or NDEA?
A. No.
Q. Or Valsartan?
A. No.
Q. Or the Valsartan drugs?
A. Correct.
Q. Other than the report that the Plaintiffs' attorneys asked you to draft and develop in this litigation have you ever written or presented or spoke outside the litigation on NDMA, NDEA or any of the Valsartan drugs?
A. No, I haven't.
Q. Since the litigation began other than your report, have you written or presented or spoken on NDMA, NDEA or any of the Valsartan drugs?
A. No, I haven't.
Q. So it's limited to this report; correct?
A. Yes.
Q. When the Plaintiffs asked -- Plaintiffs' counsel -- excuse me. Okay. I misspoke earlier.
When Plaintiffs' counsel asked you to develop a monitoring program, did they give you any more guidance

or instruction as to how to do it?
A. No.
Q. What they were looking for?
A. No.
Q. They just said develop a program and --
A. They -- they --
MR. KERNER: Go ahead. I'm sorry.
MS. GEMAN: I just want to caution you. You can speak to any facts or assumptions provided, but I don't -- I don't see Mr. Kerner is asking beyond that.
MR. KERNER: I think I heard you.
MS. GEMAN: Sorry.
MR. KERNER: That's okay. I know.
THE WITNESS: Could you repeat the question?
MR. KERNER: I'm not sure that I could.
BY MR. KERNER:
Q. When Plaintiffs' counsel asked you to develop a monitoring program, did they give you any instruction or guidance as to what they wanted?
MS. GEMAN: Objection, asked and answered.
BY THE WITNESS:
A. They advised me as to the -- the details of the case and asked if I felt that I could present a monitoring program for the group of patients that were

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identified as being at high risk for developing a group of cancers.
BY MR. KERNER:
Q. And when you said they gave you the details of the case, what did they tell you were the details?
A. The details were that it had been established by their expert reviewers and by the history of the litigation that the Valsartan tainted materials when exposed in certain amounts to patients was considered a risk for the patients ultimately developing malignancies, that these were carcinogens and then the levels that they were exposed to, that they were at risk. And part of this kind of evaluation or legal review does allow for monitoring, medical monitoring in situation, and my experience with patient care and patient -- patient -- review patient care would allow me to develop an appropriate monitoring program in that situation.
Q. Okay. You said -- and I don't want to misstate your testimony. I'm trying to remember what you just said -- that their expert reviewers established that Valsartan was considered an increased risk. Did you do any independent analysis as to Valsartan or NDMA other than what their other experts had established?
A. So my understanding, it wasn't Valsartan that

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was putting the patients at risk. It was the Valsartan that was manufactured in a way that had been tainted with these dangerous substances. I did not do independent review. That's not what I was asked to do. I was asked to just develop a monitoring program.
Q. Okay. And -- and to your point, you don't have any criticism of the drug Valsartan; correct?
A. Correct.
Q. And you're relying on the Plaintiffs' other experts for their analysis of any carcinogenic effect of the, as I think you put it, the tainted Valsartan; correct?
A. Correct.
Q. Okay. Let's get to what we're going to mark as Exhibit 3.
(Exhibit No. 3 marked as requested.)
The Zoom folks be aware of that as well.
Okay. Doctor, can you tell me what Exhibit 3 is?
A. This was the report that I provided to the -- to -- to Mr. Slater and the other attorneys.
Q. Who's Mr. Slater?
A. Mr. Slater is the one I was told to -- to

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address. One of the attorneys -- one of the attorneys for the Plaintiff.
Q. Somebody told you to address it to Mr. Slater?
A. Correct.
Q. Do you remember who told you that?
A. No.
Q. Okay. You said a moment ago that -- I think you said a moment ago that you were asked to develop a medical monitoring program, and then I think you said the legal review allows for medical monitoring in this case. That's what you said; correct?
A. I think that's what my terminology was, yes.
Q. Prior to this case have you ever created a medical monitoring program?
A. I've not developed a public medical monitoring program but I've been involved in my own patient care of -- of developing monitoring programs.
Q. What do those monitoring programs consist of? And what do you mean by monitoring programs for your patients?
A. So to get into detail, my experience in my practice includes patients that have high risk of developing cancer usually because of genetic

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abnormalities such as BRCA gene or Lynch syndrome. I follow patients and families of patients that haven't developed cancer that -- but do carry these genetic abnormalities and monitor them for malignancies.
Q. How do you do that?
A. Various ways depending on the situation.
Q. Can you explain that to me?
A. Certainly. In -- for example, in Lynch syndrome which is genetic abnormality that predisposes to gastrointestinal malignancies, I will follow the patients twice a year. The ones that do not have cancer, have not developed cancer we'll follow them twice a year with clinical exam, routine exams that include physical exam, history and basic blood analysis. I will assure that they're getting annual colonoscopies because of the high risk of developing polyposis and ultimately gastrointest -- colonic carcinoma. I will also follow them for development of uterine cancer by referring them to gynecologist by ordering radiographic studies such as ultrasounds, occasionally CAT scans.
Q. Let me interrupt you for one second, sir. For Lynch syndrome, one of the things you just said I think is that you -- you have them have an annual colonoscopy --

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A. Correct.
Q. -- correct?
Do you have all of your patients who are -- is it -- are they -- do they have Lynch syndrome or are they susceptible to Lynch syndrome?
A. No. These are patients --
MS. GEMAN: I just want to --
BY THE WITNESS:
A. -- with --
MS. GEMAN: I just want to object. The witness was not done answering the previous question, so I just want to make sure the record's clear that that wasn't an answer -- a complete answer.
MR. KERNER: Sure, and we'll come back to that in a second. I appreciate that.
MS. GEMAN: Yeah.
BY MR. KERNER:
Q. Lynch syndrome.
A. Thank you. Patients that have identified Lynch syndrome, it's recommended that they get annual colonoscopies.
Q. Are there patients who perhaps for other reasons, whether it's other history or comorbidities or something, might not be -- might not be appropriate to

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have an annual colonoscopy?
A. Yes.
Q. Can you give me an example or two of a type of patient where you wouldn't -- with Lynch syndrome where you wouldn't provide an annual colonoscopy for?
A. An elderly patient with severe cardiovascular disease, somebody that had a colonoscopy and had a complication such as a perforation, someone that just refuses.
Q. How common are perforations during colonoscopies?
A. Very uncommon.
Q. I'm sorry?
A. Very uncommon. I believe less than 1 percent. I believe less than .1 percent, but I don't know exactly.
Q. Less than .1 percent?
A. I believe so, but I don't know exactly.
Q. You don't happen to have any data or support that you can cite to me for that figure, do you?
A. No, I don't.
Q. Do you know where that figure comes from?
A. Just from my own experience in -- in practice.

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Q. So you don't know if it's a national statistic or a worldwide statistic? It's just a Kaplan statistic of less than .1 percent of perforated colons?
A. As I said, I was guessing it was either 1 percent or maybe even .1 percent. I was not opining as to the exact statistic. I know that there's literature that could answer that question.
Q. So to be fair, as you sit here right now, you don't really know how many -- what the percentage is of colonoscopy patients who have perforated colons during the procedure?
A. I know it's very rare.
Q. But you don't know what you mean by "very rare"?
MS. GEMAN: Objection.
BY MR. KERNER:
Q. What do you mean by "very rare?"
A. I've taken care of over 1,000 patients that have had colonoscopies, probably more like 3,000 patients in my career that have had colonoscopies and I've seen 2 perforations.
Q. But, again, as a good doctor who cares about his patients, you consider that as to whether a patient should have an annual colonoscopy; correct?

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A. Could you repeat that? I just got stopped at the "good doctor" because I'm glad you said that.
Q. Yeah. Strike that.
As a doctor who's concerned about his patients, I think you testified a few minutes ago that one of the reasons why you may not recommend an annual colonoscopy is if it's an elderly patient, the risk of -- the risk of a perforated colon and some other possible reasons?
A. What I said was if someone had had a perforation in their colon I would not recommend going back necessarily with a colonoscopy.
Q. Any other reasons why you might not recommend the annual colonoscopy for a Lynch syndrome patient?
A. Aside from comorbidities, risk of problems related to anesthesia, I can't think of any other reason I would not recommend an annual colonoscopy.
Q. So there are some risks that are -- that come along with a colonoscopy; correct?
A. Correct.
Q. And so what you do with your patients with Lynch syndrome is you weigh the risks versus the benefits?
A. Correct.

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Q. And in your medical judgment, as a treating physician of those patients, you make the recommendation one way or the other; correct?
A. Correct.
Q. One of the things I think you said is that -- I'll let you finish taking your notes.
A. I was saying you said I was a good doctor. Sorry.
Q. One of the things I think you said with respect to Lynch syndrome is that it is recommended that they have annual colonoscopies?
A. Correct.
Q. By whom?
A. By I believe a number of agencies. The NCCN has it in their guidelines.
Q. What's the NCCN?
A. The NCCN is the National -- I knew you were going to ask me this. I can't remember what it stands for. It's a -- it's a -- it's an organization that's -- that reviews every malignancy class and has experts from around the country and even around the world will meet regularly and create algorithms for how many conditions are treated but also for screening and for -- and for monitoring.

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Q. Is it the National Comprehensive Cancer Network?
A. That's it. Thank you.
Q. And they develop screening protocols, is that what --
A. They have recommendations in their algorithm for what should be done with patients.
Q. They're pretty well-regarded; right?
A. Yes.
Q. Do you generally follow their guidelines?
A. Generally.
Q. Are there specific guidelines that you don't follow?
A. On an individual basis I will review -- and this is usually for treating patients. I will review their recommendations, and they usually have more than one suggested direction, but we use them to -- to help decide on appropriate treatments for patients.
Q. What else do you use to decide on appropriate treatments for patients?
A. My own experience, the literature, any investigational trials that we're involved in or that we've reviewed.
Q. What about the patient him or herself?

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A. Well, of course, the patient.
Q. What do you look at with respect to the patient?
A. This is when deciding on treatment for the patient?
Q. Yes.
A. The -- the details of the patient's specific situation, the disease itself, of course, the performance status of the patient which is a measure of how functional and how sick they are, the comorbidities, patient's desires themselves.
Q. Family history?
A. In deciding on treatment, usually not.
Q. Would you take family history into account in determining whether a certain procedure is appropriate and may be more likely to be appropriate because of family history?
A. Could you explain that question?
Q. Sure. For colonoscopy would you be more likely to think a colonoscopy is appropriate annually because they have Lynch syndrome?
A. Yes. I already mentioned that Lynch --
Q. Right.
A. -- syndrome, but Lynch syndrome, although

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it's linked to family history, it's specific to that patient because they've been diagnosed with carrying the gene.
Q. Fair. What about a patient who has a first degree relative who has had colon cancer?
A. That would --
MS. GEMAN: Objection, vague.
BY THE WITNESS:
A. That would factor into my -- my assessment of the patient's own risk and the need for that patient to undergo genetic testing but wouldn't necessarily -- wouldn't necessarily at all factor into my decision about putting them through colonoscopy or any other test. It's part of the general evaluation of the patient.
BY MR. KERNER:
Q. Okay. So in terms of treatment which is what you're talking about?
A. Correct.
Q. You mentioned comorbidities. You mentioned the patient's desires. You mentioned the performance status of the patient. What do you mean by that?
A. So in part of the evaluation of a patient, and especially oncology patients that are going through treatments or are anticipating going through treatments,

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one of the ways to quantitate how the patient is doing is using a -- a table, a gauge based on a number of factors to determine how fit they are. There's two accepted methods. One is called the ECOG, Eastern Cooperative Oncology Group Performance Status, and the other is the Karnofsky Performance Status. We usually use the ECOG criteria. It's pretty straightforward. It's from zero to four. Zero is somebody that's totally asymptomatic and performing their normal day-to-day activities. One is somebody that's functional and doing everything but probably at better than 50 percent of their normal activities. Two is -- two and three and four are then progressively worse, with four being near death.

Q. And so that will help guide you with the treatment that you're going to provide for the patient; correct?

A. Correct.

Q. One of the things?

A. Correct.

Q. And is that something that NCCN also -- it's also part of their guidelines?

A. I'm not exactly sure how -- how they would use it in their guidelines. I believe they do. I think there's many studies suggesting that someone that is a

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performance status of three or worse is not likely to benefit from some of the aggressive treatments we might otherwise use that's been established. Although a lot of that's changing because of new therapies that have come out that are even appropriate for very ill patients.

Q. Okay. Let's take a look at your report.

A. Okay.

Q. And we've marked that as Exhibit 3.

You want to get that back up for the Zoom?

Okay. Did you draft this report?

A. Yes.

Q. Did Plaintiffs' counsel provide any input in the report?

A. Only typographically.

Q. And you mean literally typos --

A. Correct.

Q. -- if there were errors? That's it?

A. Yeah.

Q. Nothing else?

A. I don't believe so, no.

Q. Okay. Let's go -- in the first paragraph, "Expert Background Qualifications," you mention that you "designed screening programs for the patient I treat and frequently monitor patients at high risk for cancer or

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cancer recurrence." We've talked a little bit about that already; correct?

A. Yes.

Q. Anything about the screening programs that you said you designed for your patients that you haven't told us yet?

MS. GEMAN: Objection.

BY THE WITNESS:

A. We didn't talk about patients that have been treated for cancer, and so they're in a unique group that's going to be monitored a little differently than a healthy person that walks in that needs to be evaluated with cancer.

BY MR. KERNER:

Q. And that's where you're talking about cancer recurrence; correct?

A. Correct.

Q. So tell me what the difference is in your view with a patient who you're screening for a risk of cancer versus a cancer recurrence. Because I would assume, I shouldn't, but that somebody you're treating for cancer recurrence you might be a little bit more aggressive in terms of your -- in terms of your screening?

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A. I'm not sure what aggressive --

Q. Strike that.

A. -- means. From where?

Q. Tell me -- tell me how your screening is different for patients at high risk for cancer versus patients with cancer recurrence.

A. All of the patients will receive general evaluation. By that I mean history, a physical exam, basic laboratory studies. Patients with specific conditions will have blood tests that are designed specifically for that cancer. For example, ovarian cancer with a tumor marker called CA125 or pancreatic cancer with a tumor marker called CA929, I won't do that on a patient who didn't have the history of pancreatic cancer necessarily.

Q. Why not?

A. Because that test is designed specifically to -- to detect pancreatic cancer recurrence.

Q. Okay.

A. The other thing might be, as you alluded to, more aggressive procedures, so that might include doing CAT scans more frequently. Somebody that's had lung cancer that's been treated that had surgery but is high risk for recurrence will get CAT scans frequently.

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Q. What do you mean "frequently"?
A. I mean depending on where they are from their treatment and what their situation is and what their symptoms are. It could be -- it could be every three months, every four months, every six months, every year. It's not set in stone. It depends on the patient.
Q. And that would be true for patients who you believe are at high risk for cancer. It depends on the patient in terms of what the screening will be; correct?
A. Well, not necessarily. Patients that are at high risk for cancer that have no other symptoms or problems I will have a specific general monitoring scheme in mind which is exactly what this is all about. While as patients that have had a specific problem or have a symptom will necessitate getting additional testing done.
Q. Okay. So there are -- at least in this first section of your report, there are screening programs for patients at high risk for cancer and for cancer recurrence. Do you make any other distinctions between asymptomatic or symptomatic patients or patients with specific exposures?
MS. GEMAN: Objection.
BY THE WITNESS:
A. I'm not sure I understand the question.

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BY MR. KERNER:
Q. Okay. In your practice, when you're screening your patients, do you make any distinctions if a patient is symptomatic or asymptomatic in terms of the screening?
A. The basic screening there will be no distinction. If someone's symptomatic, that goes on from screening to evaluation. So somebody, for example, that has a cough is going to have something done more to evaluate that than someone that comes in without any symptoms, but there's a basic screening that would be provided to anybody that I identified as being at risk.
Q. At risk for what?
A. Developing cancer.
Q. Which type of cancer?
A. All -- all -- I mean it depends on what I'm seeing the patient for.
Q. Sure. So are there different screening protocols for different risks -- different cancer risks?
A. There are screening programs for -- there's individual decisions that are made based on a patient and the reason the patient's seeing me. For someone that has a high risk of developing malignancies, that could be one or could be many different types, there's going to be general screening protocols that I'll provide. An example would be someone with tobacco exposure's not just at risk for one cancer, so it would be a number of -- of procedures that are done to monitor them.
MR. KERNER: Okay. Let's take a five-minute break if we can. We've been at it a little over an hour.
THE VIDEOGRAPHER: The time is now 10:21 a.m. This is the end of media three. We're off the record.
(WHEREUPON, a break was taken.)
The time is now 10:39 a.m. This is the beginning of media four. We're back on the record.
BY MR. KERNER:
Q. Okay, Doctor. A few more questions obviously.
We're talking about paragraph 1 in your report, and I want to talk about your practice. You mentioned that you designed screening programs for certain patients. I think you testified that you have designed screening programs for patients with genetic predisposition such as BRCA or Lynch syndrome; is that correct?
A. Correct.

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Q. And also I think you said for heavy smokers? Did you say that? Do you design screening programs for patients of yours that are heavy smokers?
A. I follow guidelines for patients that have -- that are heavy smokers.
Q. Which guidelines do you follow?
A. The recommendation to do low-dose CAT scan annually which is an accepted screening protocol. It's in NCCN and I think other places as well.
Q. Are there any other categories of patients, your patients that you screen regularly?
A. I'm not sure I -- I understand the question, how to answer the question. Every patient I'm seeing is being screened regularly.
Q. Okay. Well, you mentioned that you've designed screening programs for patients. Are there any other categories of patients other than what we've just spoken about that you have designed screening programs for in your practice?
A. Patients that have family -- that have had family histories and -- of -- of -- of genetic abnormalities in high risk cancer that they themselves haven't had but because there's unknown mutations or there have been unknown mutations that may put those

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patients at risk, I will create a more intense screening program for that group of patients than for somebody that didn't have any of that history.
Q. Any other categories?
A. Not that I can think of.
Q. Okay. Scroll down to or move down to the next paragraph. You say you're compensated for this matter at an hourly rate. What is your hourly rate?
A. My hourly rate for reviewing records is $500 per hour. For deposition or courtroom testimony it's $600 per hour.
Q. So you're getting paid $600 an hour to be here today?
A. I believe so, yes.
Q. Are you confirming that? Is that what you're doing now?
A. No.
Q. What are you looking at -- is that your report?
A. That's the -- my -- my report.
Q. Okay. You also state in that paragraph that the opinions you "state in this report are stated within a reasonable degree of professional certainty." What does that mean?

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MS. GEMAN: You can take the time you need to look at the language.
BY THE WITNESS:
A. I think that's going to be true of any opinions I have about anything. Nothing is set in stone. It's going to be within what I consider -- what's considered reasonable based on my profession.
BY MR. KERNER:
Q. Tell me what you mean by "professional certainty."
A. In other words, based on my medical expertise rather than just assumptions, lay assumptions.
Q. Is professional certainty different than medical certainty?
A. Probably not.
Q. Did someone tell you to use that phrase?
A. No.
Q. Have you ever used it before?
A. I can't -- I can't recall.
Q. If you go to the top of the next page, you say that in forming your opinions you've "assumed that the people who took the Valsartan in question can be identified along with identification of the manufacturers of their pills, the dosage and levels of NDMA/NDEA and

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duration of use." What is that assumption based on?
A. Based on the information I was provided by counsel.
Q. What information was that?
A. Information we've already discussed. It was the reports of their experts.
Q. So that assumption in Section 2 is based on the reports of their experts; correct?
A. Correct.
Q. Anything else?
A. No.
Q. Okay. And you also assume "that the medical monitoring fund/program to be established can be efficiently administered to ensure that people will only receive funding for appropriate tests or intervention." What is that based on?
A. So my charge was to create a medical monitoring program for a class of patients. When I put that together, I have no knowledge as to how -- how these types of things are funded or -- or arranged logistically. I just know that -- what medically makes sense and that's what I put together in my report.
MR. KERNER: Could you read that answer back, please.

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(Requested portion of the record read.)
BY MR. KERNER:
Q. And when you say "what medically makes sense," is that based on your review of the reports from Plaintiffs' experts?
A. No. What medically makes sense is based on my -- my development of what I consider to be appropriate screening for the patients that are at risk.
Q. And what you consider to be appropriate for screening is based on what?
A. Is based on my understanding of the diseases and my review of the literature as outlined.
Q. I'm sorry. I didn't hear it.
A. As outlined in my report.
Q. What about any of the guidelines that are -- the NCCN guidelines, was that something you considered?
A. Yes.
Q. Does your screening program here vary from the NCCN guidelines?
A. The NCCN guidelines don't specifically outline the screening program especially for this particular class of patients. It just outlines details about risks and how they should be monitored.

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Q. In paragraph 3, "Background," you say: "It's been established that Valsartan API manufactured by certain manufacturers here and sold to other companies was contaminated with carcinogens, NDMA and NDEA." Do you see that?
A. Yes.
Q. And who established that?
A. I don't know who established that. I know that it's been established based on the -- on the reports that I was given.
Q. Okay. Anything else -- based on anything else or just the reports that you were given?
A. Just on the reports that I was given.
Q. Okay. Now, a little further down in paragraph 3 you mention that you constructed a monitoring protocol. The first thing you did was identify certain cancers; correct?
A. Correct.
Q. And you did that based on the review of four Plaintiffs' experts; correct?
A. Correct.
Q. So how did you do that? Explain how you did that, please.
A. Explain how I did what?

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Q. How you identified -- you said: "The following cancers merit monitoring." You reviewed the reports of these four experts, and what led you to conclude that these nine cancers merited monitoring?
A. These nine cancers were identified as those that were at higher risk based on the exposure to NDMA and NDEA.
Q. By the experts that you relied on; correct?
A. Correct.
Q. Did you consider any other cancers?
A. No.
Q. So is it your opinion, Doctor, that every proposed medical monitoring class member be screened for each of these nine cancers?
A. The screening program that I outlined would cover those nine cancers, nine classes of cancers.
Q. I understand that. We'll get to that actually, but is it your testimony and is it your opinion that all class members, proposed class members be screened for all of the nine cancers?
A. Yes.
Q. Every single class member should be screened for all nine cancers?
MS. GEMAN: Objection, asked and answered.

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BY THE WITNESS:
A. Yes.
BY MR. KERNER:
Q. What's your basis for that opinion?
A. My basis for the opinion is the evidence provided that suggests that these cancers are at increased risk of patients that have had exposure to that carcinogen and the levels they had exposure to, so they deserve to be monitored for those.
Q. And again that's based on the four Plaintiffs' experts that you referred to?
A. Correct.
Q. Is there potential for some of the proposed class members to be excluded from the screening for one or more of the nine cancers that you outlined?
MS. GEMAN: Objection to the extent it calls for a legal conclusion.
BY THE WITNESS:
A. Could you repeat the question?
BY MR. KERNER:
Q. Sure. Is there a potential for some of these proposed class members to be excluded from screening, to not be screened for one or more of the nine cancers you outlined?

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MS. GEMAN: Same objection.
BY THE WITNESS:
A. I don't understand -- I don't understand the question.
BY MR. KERNER:
Q. Do you think there are any circumstances where any of the potential class members wouldn't need to be screened for all nine of these cancers?
MS. GEMAN: Objection.
BY THE WITNESS:
A. I think the basic screening is necessary for every patient. I think individual patients would then behoove us to look at different things based on that patient, but the basic screening should be true for every patient.
Q. Let's explore that. What would you look at with respect to individual patients?
MS. GEMAN: Objection.
BY THE WITNESS:
A. You mean above and beyond the screening program that's outlined?
MR. KERNER: Can you just read back his last answer, please.

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(Requested portion of the record read.)
BY MR. KERNER:
Q. Okay, Doctor. You said it would behoove us to look at different things for different patients. What things would you look at?
A. Well, I think I mentioned in my report if somebody was a heavy smoker I may focus also on diseases associated with tobacco as I would do anyway even if they hadn't had this exposure, but this exposure may increase the risks that they have based on their own history, but yet everybody deserves at least the basic screening whatever their own history is. But any doctor's gonna look at a patient's individual problem. Someone has a pain in his arm, he's going to look at the arm.
Q. Sure. And different patients might require different screening?
MS. GEMAN: Objection.
BY THE WITNESS:
A. No. Different patients may require additional testing to the basic screening.
BY MR. KERNER:
Q. Is there any reason or could there be -- Strike that.

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Would there be any reason that you can think of based on medical history or comorbidities or anything like that for an individual patient where you wouldn't conduct the same screening for that patient? For example, would you recommend a colonoscopy every five years for someone who had a prior perforation?
MS. GEMAN: Objection.
BY THE WITNESS:
A. Well, as discussed before, a patient that's had a comorbidity or a problem related to a test would not be offered that test.
BY MR. KERNER:
Q. Sure. Okay. And say, for instance, giving another example, you list prostate cancer here in number 6. What's the appropriate screening that you propose for prostate cancer?
A. Well, first I would limit it to males.
Q. Okay.
A. The appropriate screening for prostate cancer would include a history to determine if there's any urinary symptoms, would include a physical examination which would include prostate exam as part of a regular physical and may include a blood test called a PSA.
Q. And if the person is 80 years old, would you

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recommend PSA?
A. Yes.
Q. What if they're 85 years old?
A. Depends on the clinical status of the patient. If they're 85 and fit with a good performance status, yes.
Q. Are there any male patients that you would not recommend a PSA for?
A. Patient that declined to have it. Someone that's had a -- No, strike that. I -- I can't think of any other specific situations where I would not do PSA unless there -- as we mentioned someone, that was suffering from other medical conditions that would not allow for expectation of longevity.
Q. What's the basis for performing a PSA on an 80-year old man? What's the data or the support for that?
A. Since there's no data on patients that are 80 exposed to these carcinogens and since I have seen as others have elderly patients who have developed very aggressive prostate cancer and if caught early could be -- could be given the chance not to have to suffer from progressive metastatic disease, I would recommend doing PSA even in those patients because of the unique

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situation where they've been exposed to these carcinogens.
Q. So you'd recommend a PSA for a fit 90-year old man?
A. Most likely, yes.
Q. Okay. Are there any risks to the screening procedures that you're proposing?
A. There are risks --
MS. GEMAN: Objection.
BY THE WITNESS:
A. There are risks to everything. A blood draw, the needle could break off, you could get infection, you could have pain. Most of the things I'm recommending are within the limits of accepted risk for general population.
BY MR. KERNER:
Q. Are the risks the same for all individuals?
A. No, of course not.
Q. Why not?
A. Because someone that's had a perforation from a colonoscopy may be at risk for that happening again. Someone that has other conditions of the colon which you didn't mention before like severe diverticulitis or diverticulosis may not be a good candidate for some of

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the screening. So, of course, every person has to be evaluated individually.
Q. Okay. Are there cases where the risks will outweigh the benefits?
A. We've already alluded to some of those, yes.
Q. And the answer's yes?
A. Yes.
Q. In paragraph 4 you talk about in conducting the analysis you "assumed the Plaintiffs' experts are correct that the levels, dosage and duration of use were/are sufficient to increase one's risk of certain cancers and to cause or contribute to causing cancers in users," and you prepared this report consistent with those assumptions. And you're relying on those assumptions for your opinions in this report; correct?
A. Correct.
Q. In the next paragraph you say: "In order to qualify for medical monitoring, class members must have ingested a cumulative amount of NDMA from both the Valsartan pills and their diet and they've reached the lifetime cumulative exposures associated with statistically significant increased risks in dietary and other studies." Did I read that correctly?
A. Yes.

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Q. What is lifetime cumulative exposure?
A. The amount of exposure they've had to NDMA and NDEA.
Q. Is that a term that you've used in your medical practice over the years?
A. What's that?
Q. Lifetime cumulative exposure.
A. I've used that in regards to many things -- exposure to tobacco, exposure to certain chemotherapeutic drugs where the cumulative toxicity has to do with lifetime exposure, a drug called Adriamycin. Your whole life you're at certain risk if you've had cumulative exposure, so yes, I use that term all the time.
Q. Are you familiar with the term lifetime cumulative threshold?
A. I'm -- I know what that means but what do you mean am I --
Q. So you know what it means. What does it mean to you?
A. Could you repeat the question?
Q. Lifetime cumulative threshold.
A. My assumption is that that means that when someone's reached a certain level of exposure like with radiation exposure, like with the drugs, like with these

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toxins, that they are in a class that may be at risk for developing certain things.
Q. You say that's your assumption. What is that assumption based on?
A. That's my understanding.
Q. What is that understanding based on?
A. What -- my knowledge of the English language.
Q. Okay. So is lifetime cumulative threshold a term that you've used in your medical practice over the years?
A. No. It's a term I've seen in the reports.
Q. And that's the first time you've seen it was in this report?
A. Probably.
Q. Now you talk about the cumulative amount of NDMA from both the Valsartan pills and their diet reached a lifetime cumulative exposure. You see that in that paragraph; right?
A. Can you repeat that, please.
Q. Sure. I'm sorry. In that same paragraph, you talk about that "the class member must have ingested a cumulative amount of NDMA from both the Valsartan pills and their diet that they've reached lifetime cumulative exposures." Do you see that?

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A. I do.
Q. Is NDMA something that you can be exposed to from your diet?
A. I believe that the nitrosamine -- the nitrosamines you're exposed to in -- in certain food types.
Q. What food types?
A. Prepared foods, coldcuts, bacon, things where nitrates are used as preservative or naturally occurring.
Q. What about fresh fruit?
A. I'm not -- I'm not certain.
Q. Vegetables?
A. I don't know.
Q. How can you tell the level of NDMA -- Strike that.
How can you tell whether the level of NDMA is from the Valsartan pill or your diet?
A. I don't -- I don't know that you can tell.
Q. And are you familiar with indigenous NDMA?
A. Yes.
Q. What is that?
A. NDMA that's just present in the body.
Q. You don't mention that in your report?
A. No.

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Q. Is indigenous NDMA, can that be part of a lifetime cumulative exposure?
A. Yes.
Q. So it's the Valsartan pill, it's your diet and it's the indigenous NDMA; correct --
A. Correct.
MS. GEMAN: Objection, vague.
BY MR. KERNER:
Q. -- that are all -- that all can be part of lifetime cumulative exposure as you used that term here in your report; correct?
A. Correct.
Q. And am I correct that there's no way to identify what percentage of NDMA comes from which factor -- the Valsartan pill, the diet or the indigenous NDMA?
A. I think and my understanding of the experts' evaluation is that the amount of NDMA found in the vast majority of people from indigenous or naturally occurring substances is quite lower than from a toxic -- the toxic levels that were found in the product that we're discussing, so --
Q. What -- sorry.
A. -- it's unlikely that somebody would have

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just from those other things enough exposure, enough levels to render them at significant risk. While there's so much more exposure from the tainted Valsartan, that it's -- it makes it a much more important issue.
Q. What's your basis for that statement?
A. The experts' review of this.
Q. So other than the Plaintiffs' other experts you have no idea what percentage of NDMA comes from Valsartan, diet or indigenous production; correct?
A. Correct.
Q. And, by the way, with respect to lifetime cumulative exposure, you have not independently evaluated or determined the lifetime cumulative exposure for NDMA or NDEA; correct?
A. That was not my -- my role in that. I have not done that.
Q. So I'm correct?
A. Yes.
Q. Prior to this litigation -- Strike that.
Let's go to the bottom of Page 3, please, your "Opinion on Medical Monitoring." Do you see that paragraph?
A. Yes.
Q. You say that it's your "opinion to a

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reasonable degree of medical certainty that there exists diagnostic tests that can mitigate the risks of developing cancer faced by the class of people because of their exposure to contaminated Valsartan who have a level of exposure equal to the LTC and this program --" meaning your program; correct?
A. Yes.
Q. "-- is different than the one that would have been prescribed in the absence of that particular exposure and increased risk." Did I read that correctly?
A. Yes.
Q. So a few things I want to talk to you about in that sentence. You hold an opinion to a reasonable degree of medical certainty that there are diagnostic tests that mitigate the risk of developing cancer; correct?
A. Correct.
Q. Now, you don't mean that there are tests that can prevent you from developing cancer, do you?
A. There are.
Q. What are they?
A. Colonoscopy, for example.
Q. Any others?
A. Repeat -- can you repeat the question?

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MR. KERNER: Can you read it back, please.
(Requested portion of the record read.)
BY THE WITNESS:
A. Yes. Upper endoscopy, detection of Barrett's esophagus, Pap smear, detection of pre-malignant changes. Mammogram even can detect ductal carcinoma insitu or other conditions that are considered pre-malignant. Evaluation of the liver to look for cirrhosis can predispose to the -- or fatty liver can be a precursor to developing -- to developing hepatocellular cancer. Evaluation of the pancreas can find -- can find certain ductal cystic changes that may be precursors to cancer. That's off the top of my head things that I can think of where it would predict or even prevent cancer.
BY MR. KERNER:
Q. And you talk about class of people because of their exposure to contaminated Valsartan?
A. Correct.
Q. And to that you're talking about people who have an exposure greater than or equal to the LCT which is a term you learned in your report for the first time?
A. Correct.
MS. GEMAN: Objection, misstates the

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testimony.
BY MR. KERNER:
Q. You say: "This program is different than the one that would have been prescribed in the absence of that particular exposure." Can you -- can you tell me what that sentence means?
A. The whole point of a medical monitoring program for people that have been exposed is that we're doing more than I would do with a normal, healthy person that just came in the office.
Q. Okay. But what this says is that "The program is different than one that would have been prescribed in the absence of that particular exposure." I think you mean Valsartan; correct --
A. Correct.
Q. -- and increased risk?
And you link that to the exposure being greater than or equal to the LCT; correct?
A. Correct.
Q. Do you know if it's possible to reach the LCT based on endogenous NDMA and diet without Valsartan?
A. I do not know the answer to that, but as I stated in my report, I could modify my opinion. At this point I would think that if somebody does show that

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they've reached the LCT wherever their exposure to the nitrosamines is that they would be appropriate for the screening tests that I --
Q. Even without Valsartan?
A. Yes. Yes.
Q. And so you would -- you would agree with me then that it's possible to -- Strike that.
You don't know whether it's possible to reach the lifetime cumulative threshold without Valsartan; correct?
A. Correct.
Q. And you have no idea; correct?
A. From what I've read, it sounds like it's not likely to reach the levels that were reached with the Valsartan exposure.
Q. And to be clear, when you say "from what I've read," it's from relying on Plaintiffs' other experts --
A. Correct.
Q. -- correct?
But your opinion now it sounds like has been modified to now say that if you've reached the LCT without any Valsartan exposure, you would propose the same program; correct?
MS. GEMAN: No. Objection, misstates the

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testimony.
MR. KERNER: Can you read back my question, please.
(Requested portion of the record read.)
MS. GEMAN: Vague as to --
MR. KERNER: I will rephrase that.
MS. GEMAN: Yeah.
BY MR. KERNER:
Q. If a patient reached the LCT without any Valsartan exposure, would you recommend the same program?
MS. GEMAN: Objection, vague, incomplete hypothetical.
BY THE WITNESS:
A. I was not asked to consider that, but I think it's worth evaluating.
BY MR. KERNER:
Q. And you just said you're modifying your opinion. What were you modifying your opinion to?
MS. GEMAN: Objection, misstates testimony.
BY THE WITNESS:
A. I didn't say I was modifying my opinion. I was saying I would -- I would likely include anybody that could be shown to -- as I said, someone that reached

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those levels should have this monitoring, so if that level came from somewhere else, I don't see why I wouldn't include them in that.
BY MR. KERNER:
Q. And do you do that with your patients now?
A. Do I do what?
Q. Do you screen your patients with this kind of exposure now? Do you screen your patients the way you're describing it for anybody who has achieved this LCT?
MS. GEMAN: Objection, vague.
BY THE WITNESS:
A. No, I have no way of monitoring that. I have no way of evaluating for that.
BY MR. KERNER:
Q. You have no way of evaluating what -- whether they reached the LCT?
A. Routinely -- routinely testing for levels of nitrosamines in a person's body.
Q. You're not aware of any test that can determine the lifetime cumulative threshold, are you?
A. I'm not aware of clinically available tests to monitor for that.
Q. And, again, to be specific, lifetime cumulative threshold of nitrosamine or NDMA --

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A. Correct.
Q. -- or NDEA; correct?
MS. GEMAN: I was going to jump in to say can I have that question read. You were speaking very quickly. I'm sorry.
(Requested portion of the record read.)
MS. GEMAN: Objection.
MR. KERNER: Read that back again, please.
(Requested portion of the record read.)
BY MR. KERNER:
Q. Let's move on to Page 4. You talk about specialized testing in Section 2 there. Do you see that?
A. Yes.
Q. You talk about -- is it Galleri or Galleri?
A. Galleri.
Q. And you say that "early detection or similar liquid biopsy should be performed annually." On Page 5 you again mention Galleri, and you say that "it has been shown to detect certain cancers such as pancreatic and esophageal cancer." Where is the -- what is the data to support annual Galleri testing?
MS. GEMAN: Objection.

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BY THE WITNESS:
A. The recommendation to do annual testing is based on my own program recommending screening, and I'm recommending the patient be seen by a physician at least annually, so I would include that as part of the routine blood tests and evaluations.
Q. Right. And my question is a little different. Other than your own recommendation, and I appreciate that, what is the data that supports Galleri, Galleri's annual testing?
MS. GEMAN: Vague.
BY THE WITNESS:
A. There's data that shows Galleri can detect cancers in earlier stages.
BY MR. KERNER:
Q. And is that part of any guidelines from NCCN or any other organization?
A. No.
Q. Do you know of any organization that recommends annual testing with Galleri?
A. I know that the American Cancer Society has -- has suggested utilizing this test for evaluating patients, and they're involved in -- in co -- in sponsoring of a bill that -- that was brought to Congress

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in August to allow Medicare to -- to insist that Medicare cover this testing because of its -- its ability to detect cancers earlier.
MR. KERNER: Great. I move to strike that as nonresponsive.
BY MR. KERNER:
Q. My question is do you know of any guidelines or any organization that supports annual testing of Galleri.
A. No.
MS. GEMAN: Objection, asked and answered.
MR. KERNER: Now it's been answered.
BY MR. KERNER:
Q. You mentioned that Galleri has been shown to detect certain cancers such as pancreatic and esophageal cancer; correct?
A. Correct.
Q. That's what it says.
Okay. You also recommend Cologuard for colon cancer?
A. Correct.
Q. And you recommend colonoscopy every five years and an upper endoscopy every five years; correct?
A. Correct.

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Q. So for every patient who has -- every patient on the planet who has achieved this LCT that you've learned of in this litigation for the first time, you want them to have a colonoscopy and an upper GI endoscopy every five years?
MS. GEMAN: Objection, misstates the opinion, misstates testimony, misstates the report, calls for a legal conclusion by the class definition.
BY MR. KERNER:
Q. Is that correct?
A. I don't understand.
Q. Any class member, any proposed class member you're suggesting -- Strike that.
You're recommending that every single proposed class member has a colonoscopy and an upper endoscopy every five years regardless of comorbidities, regardless of other past history; correct?
A. My recommendations are guidelines that are recommendations for patients and their doctors to consider using, so that would be taken into account when deciding on that test.
Q. So -- okay. I appreciate that. And so am I correct that you think ultimately the decision is to be made by the individual and his or her treating physician

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as to what particular procedure is appropriate for them, for that person?
A. I'm -- I'm outlining a guideline because of the exposure that can help guide the patient and the doctor in determining -- in determining whether to follow exactly the guideline or make individual recommendations, yes.
Q. And I didn't include the low-dose CT chest scan annually. It's your recommendation that any proposed class member has a CT scan once a year?
A. No, I don't believe I said that.
(Witness peruses document.)
Q. Page 4.
A. Okay.
Q. You do say that; correct?
A. Yes. I'm sorry. Because of the exposure that put them at the same risk as someone who'd been a smoker.
Q. And your opinion -- that's your opinion, that the exposure to NDMA or nitrosamines puts them at the same risk as a smoker?
A. Based on the estimate of exposure and risk of lung cancer from that exposure, yes.
Q. On whose estimate? Based on whose estimate?

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A. The Plaintiff experts that estimated the relative risk of 1.05 to 3.3 for lung cancer.
Q. So, again, this is basically just based on what the Plaintiffs' experts have opined; correct?
A. Correct.
Q. So, Doctor, what I see in your report is you seem to be recommending in some form or another the Galleri which you say can detect certain cancers such as pancreatic and esophageal; correct?
A. Can you tell me where you're looking, please.
Q. Yeah. That's on Page 5. Under "Colonoscopy and Fecal DNA testing" you mention that -- I'm sorry. Under "Galleri" you mention that Galleri is known to detect certain cancers such as pancreatic and esophageal. Do you see that?
A. Yes.
Q. Okay. And you also have a section on colonoscopy for detecting colon or rectal cancer; correct?
A. Correct.
Q. And then you also discuss a little further up I believe, and we just talked about it briefly, the CT chest scan. Is that for lung cancer?
A. Yes.

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Q. Okay. I don't see any other screening identified in your report. Do you -- do you think that those are the -- are those the cancers that you would screen for -- pancreatic, esophageal, colorectal and lung cancer?
MS. GEMAN: Objection, misstates testimony, asked and answered.
BY THE WITNESS:
A. There's two things there. There's -- the first is that the Galleri, what you're reading is using pancreatic and esophageal as examples. It's not listing all the cancers it's screening for, and the reason it was listed as examples is because there's not good screening -- screening tests for detecting those early. The Galleri could, but the Galleri's good for almost every cancer. That's the point of the Galleri. The -- the other thing is that's not the only testing. If you look in my program, it includes the annual laboratory studies, exam, history, and those that you're referring to are just specialized testing in addition that I felt was -- was appropriate in order to help detect cancer in earlier stages.
BY MR. KERNER:
Q. Where in your report do you talk about

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screening for bladder cancer?
A. So I don't talk specifically about bladder cancer. It's listed with the other cancers in here, and that would be included in the history because there'll be unique things to -- to patients that have bladder cancer. In the physical examination, laboratory tests could determine -- could be a way to screen for bladder along with others and then the Galleri which can also detect urinary tract cancers and other cancers in earlier stages.
Q. And what about liver cancer?
A. And liver cancer as well.
Q. Galleri?
A. Galleri, but also the things we mentioned. Liver cancer would have signs usually of cirrhosis or hepatic steatosis, fatty liver, and that can be detected by examinations and by laboratory tests and by history.
Q. And if you can help me out here. Which laboratory tests in your report are you referring to with respect to liver cancer?
A. Liver enzymes.
Q. Where is that?
A. 1C: "Laboratory tests to include blood smear, basic chemistry profile which includes liver

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enzymes, kidney function and other labs."
Q. Okay. Doctor, in paragraph 6 or Section 6, you say midway through the paragraph that you "certify that the monitoring proposals detailed above have the potential to significantly improve the outcomes of patients that may be destined to develop malignancies due to their exposures and do not pose any significant risks or negative consequences." Do you see that?
MS. GEMAN: Just object to the extent --
MR. KERNER: Excuse me?
MS. GEMAN: I just note that the report speaks for itself.
MR. KERNER: Sure.
MS. GEMAN: You're paraphrasing.
BY MR. KERNER:
Q. Well, what I read, did I read that correctly?
A. Yes.
Q. Okay. What do you mean by "I certify that the monitoring proposals have the potential to significantly improve the outcomes?" Are you guaranteeing it?
MS. GEMAN: Objection.
BY THE WITNESS:
A. Is your question what do I mean by "certify"?

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BY MR. KERNER:
Q. Yes, sir.
A. It means that to the best of my medical knowledge and ability I believe that this does what it's stated to do.
Q. It's your opinion?
A. Correct.
Q. Did somebody tell you to use the word "certify" in there?
A. No.
Q. You also say that: "These exposures do not pose any --" I'm sorry. "This monitoring proposal do not pose any significant risks or negative consequences."
MS. GEMAN: Objection. Again, it misstates the report. It says: "As detailed in Dr. Catenacci's report."
MR. KERNER: Yes.
BY THE WITNESS:
A. There's a report that's been stricken, and the details of that report is what I was addressing.
BY MR. KERNER:
Q. But we would agree, I think you've already agreed, that there could be risks or negative consequences to certain procedures; correct?

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MS. GEMAN: Objection, vague.
BY THE WITNESS:
A. As I stated before, anything you do including a needle stick or walking in a room -- I didn't state that before; I'm stating it now -- has risks.
Q. And that's all I'm asking, right.
MS. GEMAN: Objection, calls for speculation.
BY MR. KERNER:
Q. Doctor, in your practice, have you ever concluded that any patient's cancer was caused by NDMA or NDEA?
A. I've never had the opportunity to do that, no.
Q. So the answer's no, you have not?
MS. GEMAN: Objection, asked and answered.
BY THE WITNESS:
A. No.
BY MR. KERNER:
Q. Over the course of your career how many patients have you treated ballpark?
A. 20,000 to 30,000.
Q. Out of that universe of patients, how many of them were cancer patients?
A. Eighty percent.

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Q. Okay. Out of that number, how many of those patients did you make a determination as to the actual cause of their cancer?
A. I'm actually not in the habit of making determination as to cause of cancers usually.
Q. And you're not opining here about causation of any of the proposed class members; correct?
A. Correct.
Q. In your report on Page 4, in C you talk about "Periodic testing." Do you see that?
A. Yes.
Q. And for the colonoscopy you do say every five years as for screening in moderately high risk patients?
A. Correct.
Q. What makes a patient moderately high risk?
A. I believe that's outlined in the NCCN guidelines, but moderately high risk patients would be somebody that had had a polyp, a pre-malignant polyp, an adenomatous polyp. I think that would be the main definition.
Q. With the proposed class members, have you considered in your program the likelihood of reduced mortality?
A. Could you --

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Q. Are you considering whether the screening is appropriate?
A. Could you repeat the question?
MR. KERNER: Can you read it back, please.
(Requested portion of the record read.)
BY THE WITNESS:
A. I believe by definition of what we're doing the point is to reduce mortality and morbidity.
BY MR. KERNER:
Q. And do we have -- do you have, Doctor, any specific data for each of the tests that you're proposing on whether it, in fact, does that?
A. Not specifically, no.
Q. This is just your -- Well, strike that. Okay.
A. Could we go back to that last question?
Q. Sure.
THE WITNESS: Can you read that back?
(Requested portion of the record read.)
BY THE WITNESS:
A. I mean there is data, for example, with low-dose CAT scans for lung cancer that it does reduce

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morbidity and mortality by detecting cancer earlier, so there is data. You asked if I specifically had data for this, so that's the answer.
MR. KERNER: Okay. I actually need to take a two-minute comfort break, and we'll come right back.
THE VIDEOGRAPHER: The time now is 11:34 a.m. This is the end of media four. We're off the record.
(WHEREUPON, a break was taken.)
The time is now 11:56 a.m. This is the beginning of media five. We're back on the record.
BY MR. KERNER:
Q. Dr. Kaplan, we're not quite there yet, so we're going to just keep chugging along. All right?
A. Yes, sir.
Q. All right. A few questions here.
You can't point to any medical literature or authoritative source that has actually determined that exposure to NDMA or NDEA reasonably necessitates any sort of medical monitoring for cancer in humans, can you?
MS. GEMAN: Objection.
BY THE WITNESS:
A. Can you repeat that, please.

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BY MR. KERNER:
Q. Sure. You can't point to any medical literature or authoritative source that has actually determined that exposure to NDMA or NDEA reasonably necessitates the kind of medical monitoring for cancer in humans, can you?
MS. GEMAN: Objection.
BY THE WITNESS:
A. I haven't investigated that. I know literature exists because the reports that have come out were based on it. Plus I know the FDA withdrew the drug in a -- in a rapid manner because of their determination there was some risk. That's all I know.
BY MR. KERNER:
Q. Okay. So but my question is are you aware of any medical literature or authoritative source that determined the kind of medical monitoring that you're proposing for cancer in humans is appropriate for -- because of exposure to NDMA or NDEA.
MS. GEMAN: Objection, asked and answered, vague.
BY THE WITNESS:
A. There's medical literature to support the monitoring for patients at risk, at similar risk to what

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we've determined or what has been determined for the risk for the specific agents but no, not literature specifically that I know of addressing that and the monitoring.
BY MR. KERNER:
Q. And by "that" you mean NDMA and NDEA?
A. NDMA and NDEA, correct.
Q. So the answer to my question is no, you're not aware of any medical literature or authoritative source that determined medical monitoring for NDMA -- as a result of NDMA and NDEA exposure is appropriate --
MS. GEMAN: Objection.
BY MR. KERNER:
Q. -- correct?
A. I've never seen literature that -- yes.
MR. KERNER: Did you get that?
THE REPORTER: Yes.
MR. KERNER: I just saw you tilt your head.
BY MR. KERNER:
Q. Doctor, you're not offering any specific criticisms or opinions about what a specific Defendant did or didn't do with respect to Valsartan, are you?
A. I'm not opining to that, no.
Q. And you're not offering any opinion that NDMA

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or NDEA causes cancer, are you?
A. I'm not being asked to opine to that.
Q. So you're not?
A. I'm using that assumption.
Q. But you -- you're not offering the opinion that NDMA or NDEA causes cancer; correct?
A. I'm suggesting that that's a truism which is why I've created this monitoring, so I guess I'm offering that opinion based on -- I'm offering that as a statement of fact.
Q. Based on what?
A. Based on the reports I've read.
Q. You haven't independently assessed the carcinogenicity of NDMA or NDEA; correct?
A. Correct, I have not independently assessed any of that.
Q. And you're not offering any opinion that Defendants' Valsartan products cause cancer; correct?
A. Could you repeat that, please.
Q. Sure. I'm going to do it this way. You haven't independently assessed the -- whether or not the Defendants' Valsartan products cause cancer?
A. I have not independently assessed that.
Q. So you won't be opining on that; correct?

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A. I won't be opining on -- I won't -- I really --
MS. GEMAN: Do you understand the question?
MR. KERNER: Yeah.
MS. GEMAN: Answer it.
BY THE WITNESS:
A. Well, not exactly. I'm not specifically looking at the data to opine that the drugs with the contaminants have led to cancer, but I'm using others who have done that in order to -- to justify and create my program.
BY MR. KERNER:
Q. I understand that. And the others, again, I want to be specific, are the Plaintiffs' experts --
A. Correct.
Q. -- correct?
Doctor, I'm going to move -- I'm going to end my testimony -- end my questioning for the time being, but a couple of ministerial things first.
Rachel, as we talked about, we've got -- I want to mark as Exhibit 4 the thumb drive that we discussed which contains the files that you produced on Monday. So we'll mark that as Exhibit 4. You can review it. You can look at it to make sure it is what we tell

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you it is, and I know we discussed this off the record. I don't want to take a lot of time.
And, Doctor, I just want to make sure. You've told me all of your opinions that you hold with respect to the case now; correct?
A. I've -- all that I've been asked about, yes.
Q. Well, are there other opinions that you hold that you are going to testify to?
A. Not that I know of.
Q. Okay. And so we've discussed the facts that support those opinions; correct?
A. Correct.
Q. And you feel like you've had a chance to state your opinions during this deposition?
MS. GEMAN: Objection.
BY THE WITNESS:
A. Yes.
MR. KERNER: Okay. I'm going to pass the witness now.
MS. ISIDRO: Are there others on the Zoom who would like to ask any questions?
MS. LOTMAN: Yes. This is Alyson Lotman. I'm going to have a few. Give me one minute.
MS. GEMAN: Alyson, can you state your

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appearance and which Defendant you represent and firm? This is Rachel Geman speaking. Thank you.
MS. LOTMAN: Alyson Lotman from Duane Morris. I represent the HP Defendants.
I apologize. If someone else has a few, wants to go before me. I'm just trying to close some screens before I can get on.
Are we still on the record?
THE VIDEOGRAPHER: Yes.
MR. KERNER: Yes.
MS. GEMAN: Yes.
MS. LOTMAN: Thanks.
Good afternoon, Dr. Kaplan. Can you hear me and see me okay?
THE WITNESS: I can hear you. You're a little picture up there, yeah.
MS. LOTMAN: It might be better that way.
THE WITNESS: I'd rather not look at myself so.
MS. LOTMAN: I understand that feeling. Happens to me a lot when I'm on Zoom.
A few questions for you then, Doctor.

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CROSS EXAMINATION
BY MS. LOTMAN:
Q. How long did it take for you to develop this plan, medical monitoring plan in your report?
A. I would say about -- about a month, three or four weeks.
Q. Okay. And over the course of that time how many -- how many hours do you think you actually spent on it?
A. It should be documented. I think it was probably about 12 to -- probably about 20 hours.
Q. Okay. And that includes -- does that include reviewing literature?
A. Yes.
Q. And writing the report itself?
A. Correct.
Q. How long do you think it took you to actually formulate your opinions?
MS. GEMAN: Objection.
BY THE WITNESS:
A. Ten, twelve hours.
BY MS. LOTMAN:
Q. And, Doctor, have you ever -- have you ever crafted a medical monitoring plan such as this for

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litigation before?
A. No.
Q. Have you ever published on medical monitoring?
A. I have not.
Q. Then, Doctor, you talked before about you have your private practice. You have patients who are asymptomatic but they have certain genetic issues like BRCA; right?
A. Correct.
Q. And so you are conducting additional monitoring because of that genetic issue; right?
A. Correct.
Q. Okay. For patients who -- do you see any other patients who are asymptomatic who don't have genetic issues?
A. Could you -- could you rephrase it? Do I see any patients?
Q. Sure. Sure. So do you also have any other patients who treat with you who are asymptomatic but did not have a prior cancer who do not have genetic issues?
MS. GEMAN: Objection, vague.
BY THE WITNESS:
A. Do I have --

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BY MS. LOTMAN:
Q. Let me reask it --
A. Okay.
Q. -- because I think it's a little unclear. You have patients who have cancer at your practice; right?
A. Correct.
Q. Do you have patients who have certain genetic issues or mutations or elements that you are concerned about like BRCA?
A. Do I -- I couldn't hear you.
Q. You also treat -- sorry. You also treat patients who have certain genetics like BRCA that you treat as well, you're monitoring?
A. Yes.
Q. Are there any other types of patients that you see?
A. Yes.
Q. Okay. What are they or who are they?
A. You want their names and phone numbers?
Q. No, Doctor. I'm just looking for what is their concern that they're seeing an oncologist.
A. So I happen to have a handful of patients that do not see me for oncology, that see me for internal

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medicine either because they were related to a member of the family that I took care of or I know them from the community or from other people, so I do have some general internal medicine patients but not very many. I don't consider myself a general internist, but you have to be to some degree a general internist in order to be a medical oncologist. I do see patients that have had abnormal findings, for example, Barrett's esophagus or -- well, we mentioned genetic like Lynch syndrome, people have had multiple polyps that haven't been identified as having a genetic -- a genetic condition that's been identified. I do follow patients that have had variants of the genetic -- like the BRCA that are variants of uncertain significance and so they'll be monitored to a certain degree, not the same as a known deleterious mutation or known risk mutation but the possibility that it is going to be identified as one, so they're -- they're followed, and then other patients are just concerned. I've had people come in that are just concerned about their cancer risk, and I also take care of some patients with blood disorders.
Q. Okay. Doctor, for your patients who smoke, you follow the USPSTF guidelines for screening?
A. I do.

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Q. Are you aware that tobacco is a known human carcinogen?
A. I am.
Q. Okay. And you don't recommend any extra screening for those patients who have exposures to tobacco?
A. No, I do. I -- I recommend a number of screening procedures for them, mostly the things we've outlined before -- the annual exams or blood tests, urine tests.
Q. But you don't go to the same specialized plan that you do for the patients in this case?
MS. GEMAN: Objection.
BY THE WITNESS:
A. I have not developed a specialized program for that group of patients at this time.
BY MS. LOTMAN:
Q. So you treat patients who have exposure to tobacco, a known human carcinogen, and you don't recommend that they have the same types of tests, the specialized testing that you've recommended for the patients who have alleged exposure to nitrosamines?
MS. GEMAN: Objection, misstates the testimony.

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BY THE WITNESS:
A. I don't have a class program for those patients I've -- that I've recommended. I don't have large enough numbers that I'm seeing, and I haven't been asked to do that.
BY MS. LOTMAN:
Q. So for your patients who smoke, you don't have them go through the Galleri? They don't have Galleri testing, do they?
A. No, but that's something that I intend to start doing.
Q. When do you intend to start doing that?
A. Soon. I've already ordered the test a few times. I've recently learned about the test and evaluated its usefulness and have learned more about it, and so I'm starting to order it or recommend it for patients.
Q. How do you order it?
A. It's a prescription. It's a kit. You draw blood and you send it off in a kit to the company.
Q. Does Galleri currently have FDA approval?
A. Galleri does not yet have FDA approval. It does have CLIA certification.
Q. But does not have FDA approval?

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A. Not yet, no. But many tests that we do don't have FDA approval, blood tests in the office, other things, but yeah, you're right. It does not yet have FDA approval. They're attempting to get FDA approval.
Q. Doctor, do you know the difference between a known human carcinogen and a probable human carcinogen?
A. I'm assuming a known human carcinogen has been proven to cause cancer. Usually -- I mean in humans most of the probable human carcinogens are based on animal studies and epidemiologic studies.
Q. Okay. Do you know what a probable human carcinogen is?
A. So I'm saying probable is something that's been shown in, probably in animal studies to increase risk of cancer and to suggest that there's a human risk as well.
Q. Suggest not -- not a -- not know?
A. I'm sorry?
Q. You said suggest and probable; right, for the probable one? There's not a known carcinogen? There's a difference; right?
A. Well, known human carcinogen may be a proven carcinogen in the laboratory or in animal studies.
Q. Okay. Would you make the same about say

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medical monitoring for a probable human carcinogen as you would for a known human carcinogen?
MS. GEMAN: Objection, incomplete hypothetical.
BY THE WITNESS:
A. I haven't thought of that, so I don't have an answer.
MS. LOTMAN: Okay. Those are all of my questions.
Thank you very much for your time, Doctor.
THE WITNESS: Sure.
MR. KERNER: Anybody else have any questions?
(No response.)
Well, if nobody else has any questions, I do very quickly.
I just want to mark another exhibit.
(Exhibit No. 5 marked as requested.)
MS. GEMAN: This is 5.
MR. KERNER: This is 5. For the Zoom folks, it says "Invoices."
MS. GEMAN: So in my copy it's three -- yeah, it's three identical pages of October 22nd.
THE WITNESS: I have the same thing. Oh, it's

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October 7th -- I mean November 7th to November 10th.
MR. KERNER: Okay. Let's do it this way.
MS. ISIDRO: Go off the record.
MR. KERNER: Yeah. Let's go off the record for a second.
THE VIDEOGRAPHER: The time now is 12:15. This is the end of media five. We're off the record.
(WHEREUPON, a break was taken.)
The time is 12:17 p.m. This is the beginning of media six. We're back on the record.
REDIRECT EXAMINATION
BY MR. KERNER:
Q. Okay, Doctor. We just wanted to mark Exhibit 5 and talk about them real quickly. Can you tell us what Exhibit 5 is?
A. My invoices to -- to the lawyers.
Q. And how many invoices are there?
A. There are four in front of me.
Q. Okay. And they're all addressed to Nicholas Migliaccio?
A. Correct.
Q. Does that sound right?
A. Correct.

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Q. Who is that?
A. It's the attorney that is -- one of the attorneys involved in this case.
Q. Okay. But he's not the one who contacted you initially?
A. No, I think he's the first one that I spoke to or one of the first ones that I spoke to. I can't recall.
Q. Okay. So it was not at Lieff Cabraser as you testified earlier?
MS. GEMAN: Objection, misstates testimony.
BY THE WITNESS:
A. She's one of the attorneys also that I -- I didn't remember who it was that contacted me first, but she's one that's been on all of our meetings.
BY MR. KERNER:
Q. But Mr. Migliaccio was the first one to contact you?
MS. GEMAN: Objection.
BY THE WITNESS:
A. I don't recall exactly who was the first one to contact. That's the one who I was told to send the invoices to.

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BY MR. KERNER:
Q. Okay. Fair enough. So you -- on October 22nd, 2001 you sent an invoice for a retainer of $2,000?
MS. GEMAN: 2021 not 2001.
MR. KERNER: Oh, gosh, yeah. October 22nd, 2021.
MS. GEMAN: We're not that slow.
BY MR. KERNER:
Q. And that was for $2,000; correct?
A. Correct.
Q. Has that been paid?
A. Yes.
Q. And then the next invoice is November 5th, 2021 and that looks to be for time spent from October 20th to November 5th, and you spent 20 hours during that time frame for teleconferences and communication, review of literature, analyses and report review; correct?
A. Correct.
Q. Okay. And you billed that out at $450 an hour?
A. Correct.
Q. And so the invoice is for $11,250; correct?
A. Correct.

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Q. Was that paid?
A. Yes, I believe so.
Q. And the third invoice is five days later dated November 10th, and that was for time spent from November 7th to November 10th of 2021; correct?
A. Correct.
Q. And that also was for teleconferences and communication, review of literature, analyses and report review and writing and correcting reports; correct?
A. Correct.
Q. And you spent 11 hours?
A. Correct.
Q. Also billed out at $450 an hour. I guess there's a .25 percent charge added onto it?
A. Right.
Q. What's that?
A. It was because it was -- there was a time limit. It was rushed, not rushed, but there was a deadline to get it in, so I had to work within a shorter time frame.
Q. Got it. And, by the way, the prior invoice on November 5th had that same --
A. Correct.
Q. -- .25 percent?

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A. Correct.
Q. So this third invoice was for $6,187.50, also billed out at $450 an hour; correct?
A. Correct.
Q. And the final invoice that we have is dated December 31st, 2021 for time spent from December 16th to December 31st for teleconference and review of records; correct?
A. Correct.
Q. What records did you review?
A. I don't know the exact records. It's all the references that we had. It was discussing my report with the lawyers. I can't remember specifically.
Q. Okay. And you spent 11 hours according to the invoice?
A. Correct.
Q. And there was no .25 percent charge on this one; correct?
A. Correct.
Q. And so the total amount due was 5500?
A. Correct.
Q. Has that been paid?
A. I don't think so. I don't -- I don't remember.

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Q. Okay. So -- so overall it looks as though you spent 44 hours --
A. Okay.
Q. -- correct?
And you charged approximately $24,000 and change; correct?
A. Okay. I hadn't added it up.
Q. Will you be providing any additional invoices for time since December 31st?
A. Yes.
Q. Do you have any idea how many hours you've spent since then?
A. In preparing for the deposition, probably another 20 hours --
Q. And --
A. -- including the deposition.
Q. Including the deposition.
Okay. And I think you told us your rate for the deposition was $600 an hour?
A. Correct.
Q. By the way, I note that on the last invoice dated December 31st you billed 11 hours at $500 an hour, so your rate went up from November 10th to December 16th?
A. Inflation.

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Q. An extra 50 bucks an hour?
A. Yeah.
MR. KERNER: Okay. That's all I have.
THE WITNESS: Okay.
MR. KERNER: Anybody else has anything, speak now.
MR. GEOPPINGER: Yeah, I have a couple questions, if I may. Good afternoon, Doctor. My name is Jeff Geoppinger. I'm here on behalf of Amerisource Bergen. Can you see me now?
THE WITNESS: Sort of, yes.
MR. GEOPPINGER: Good afternoon. Again, my name is Jeff Geoppinger. I represent Amerisource Bergen in this litigation. I just have a real quick couple follow-up questions.

CROSS EXAMINATION

BY MR. GEOPPINGER:
Q. Earlier when you were talking to Ms. Lotman, you mentioned you have patients who you treat who are just concerned about cancer risk. Did I hear that correctly?
A. Yes.
Q. Are those patients asymptomatic?
A. I think many of them are. There aren't a lot

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of them in that category, but there are some who are asymptomatic.
Q. I understand. They don't have an active cancer diagnosis; correct?
A. Correct.
Q. And they don't have any genetic conditions that would predispose them to cancer that they're concerned about or that you're concerned about; correct?
A. None that had been identified, yes.
Q. Okay. So for those patients, what do you do to treat them?
A. So they're not being treated. They're being monitored, and it includes basic -- basic exam, something they may get from their internist but with more focus on cancers.
Q. And is that screening the same for all of those patients or does it vary by, you know, individual patient?
A. The basic screening is the same for all of them because they need to have a good exam, they need to have basic laboratory tests, and they need a good history, and I'm finding many of them aren't getting those things done in their general practices, in the primary practice because of very busy doctors, so I'll be

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a little more -- I'll take longer, and I'll be a little more detailed, but everybody will get a basic screening. If there's anything discovered, then they would go on to get more unique tests done.

Q. I'm sorry. I didn't hear the end of that answer. What was that you said, Doctor?

A. They're all screened the same way. That's what I wanted to say.

Q. Okay. And do -- after the basic screening that they all get the same way do some of those patients get additional screening based upon what you find after you do the basic screening?

A. Yes.

Q. Okay. And do they all get the same additional screening or does it vary by patient?

A. It would vary by what the reason is for doing the additional screening.

Q. Okay. Now I'm going to ask you a hypothetical. If one of those asymptomatic patients provided you information that they had -- they ate a lot of bacon or that they had taken Valsartan between 2012 and 2018, would your screening of that patient change in any way?

MS. GEMAN: Objection, incomplete

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hypothetical, compound.

BY THE WITNESS:

A. It would depend. I'd have to be there with the patient and see -- hear everything about it. I can't answer that question with what you've told me.

BY MR. GEOPPINGER:

Q. Would it be accurate to say that you would make an individual determination about the screening in that case --

MS. GEMAN: Objection.

BY MR. GEOPPINGER:

Q. -- for the patient?

A. After the initial evaluation I would make an independent decision just like with any patient including Valsartan-exposed patients after they've gone through the screening I've recommended.

Q. Okay. So in my hypothetical I have an asymptomatic patient who tells you that they have -- that they had foods in their diet that may include NDMA, that they may have been taking Valsartan-containing products from 2012 to 2018. In that situation, would your process for treating an asymptomatic patient be any different than it would be in treating the asymptomatic patients you see right now?

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MS. GEMAN: Objection, asked and answered, incomplete hypothetical, vague.

BY THE WITNESS:

A. The Valsartan is not -- is not a deal -- a detail that I can answer to because the patients we're dealing with have levels that have been proven, have been identified to be in a class. You're talking about an individual person who's taking the drug. I wouldn't have any -- right now any -- a plan of how to specifically address that patient. They would need the same monitoring and the same -- I mean the same evaluation that the patients in the class have had to determine their level of -- of exposure, et cetera.

BY MR. GEOPPINGER:

Q. Would it be accurate to say you would treat that patient just like you do the asymptomatic patients you treat now?

MS. GEMAN: Objection.

BY THE WITNESS:

A. Again, it depends on -- on the situation of the patient that I have in front of me. To take one patient is very difficult to answer. It's not a real patient.

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BY MR. GEOPPINGER:

Q. Would you give -- would you recommend for that patient who reveals to you the -- their history of dietary intake of NDMA and potential history of VCB usage and NDMA, would you automatically screen them for all the conditions that you've listed in your report?

MS. GEMAN: Objection, incomplete hypothetical.

BY THE WITNESS:

A. Just on the basis of that history I wouldn't necessarily do anything different than what we've already discussed.

MR. GEOPPINGER: Thank you, Doctor. I don't have any further questions.

MR. KERNER: Anyone else?

MS. LOTMAN: If I may, Doctor. This is Alyson Lotman. I have one more question. I think it's just one.

RECROSS EXAMINATION

BY MS. LOTMAN:

Q. Who do you recommend to do these screenings?

MS. GEMAN: Objection.

BY THE WITNESS:

A. I don't understand your question. Who do I

recommend?
BY MS. LOTMAN:
Q. If these -- if the patients were to get the screening that you recommended here, who should be administering it?
A. Well, as I outlined in my report, it would be either the primary care doctor or an oncologist or a general practitioner, a family practitioner, somebody that would be made aware usually through the patient telling them that they have this exposure, this risk and they have this recommended guideline for screening.
Q. And if their doctor decided that based upon their comorbidities or their medical history that these were unnecessary, do you believe that your plan should stand in place of that doctor's judgment?
MS. GEMAN: Objection, incomplete hypothetical.
BY THE WITNESS:
A. My plan is a guideline, just like the NCCN has their guidelines, and it's up to the individual practitioner to -- to decide based on the individual patient what is appropriate for them.
MS. LOTMAN: Thank you very much, Doctor.
MS. GEMAN: Are there any other questions from

the Defendants?
(No response.)
Do you have it on your screen? Did people write in?
MS. ISIDRO: No one else on the Zoom?
MS. GEMAN: Do you formally conclude it and pass it to me? How are we doing this?
MR. KERNER: Yeah, if none of the Defendants have any questions and you have questions, ask away.
MS. GEMAN: Thank you.
CROSS EXAMINATION
BY MS. GEMAN:
Q. Dr. Kaplan, what is CLIA certification?
A. CLIA certification is -- is certification that's given by a board that -- that attests to the accuracy and the usefulness of a particular test, that it's considered accurate and it does have some impact for the patient.
Q. Okay. Can you please take out what's been marked as Exhibit 3 and turn to Page 3. Does the class as set forth on Page 3 capture the population of people for whom you are recommending your monitoring program?
A. Yes.
Q. I think there was some confusion before.

You're not recommending that this monitoring program be provided to people who did not take the contaminated Valsartan, i.e. you are not recommending this program to, this exact program to non-class members; correct?
A. The point of this program was medical monitoring for those that had been identified as being at risk because of their intake of Valsartan-contaminated products.
MS. GEMAN: Okay. Thank you for the clarification.
Okay. We'd like to read and sign.
MR. KERNER: Yeah.
THE VIDEOGRAPHER: The time is now 12:33 p.m. This is the end of media six.
This concludes this deposition. We're off the record.
THE REPORTER: Would anyone like a copy of the transcript?
MR. STOY: This is Frank Stoy. I'd like an electronic copy, please.
MS. LOTMAN: Alyson Lotman. I'd like the same.
MR. CHARCHALIS: (Inaudible).
MS. ISIDRO: Mitchell wants an electronic.

STATE OF ILLINOIS)
) SS:
COUNTY OF C O O K)

I, KELLY A. BRICHETTO, a Certified Shorthand Reporter of said state, do hereby certify that the within named witness, EDWARD H. KAPLAN, M.D., was by me first duly sworn to testify the truth, the whole truth and nothing but the truth in the cause aforesaid; that the testimony then given by the above-referenced witness was by me reduced to stenotype in the presence of said witness; afterwards transcribed, and that the foregoing is a true and correct transcription of the testimony so given by the above-referenced witness.

I do further certify that this deposition was taken at the time and place in the foregoing caption specified and was completed without adjournment.

I do further certify that I am not a relative, counsel or attorney for either party or otherwise interested in the event of this action.

IN WITNESS WHEREOF, I do hereunto set my hand this 21st day of January, 2022.

Kelly Brichetto

KELLY A. BRICHETTO
CSR License No. 84-3252

RACHEL J. GEMAN
rgeman@lchb.com
January 26, 2022
RE: In Re: Valsartan, Losartan, Et Al
1/19/2022, Edward H Kaplan , MD (#5025121)
The above-referenced transcript is available for review.
Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.
The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at erratas-cs@veritext.com

Return completed errata within 30 days from receipt of testimony.
If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

In Re: Valsartan, Losartan, Et Al v.
Edward H Kaplan , MD (#5025121)
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Edward H Kaplan , MD Date

In Re: Valsartan, Losartan, Et Al v.
Edward H Kaplan , MD (#5025121)
ACKNOWLEDGEMENT OF DEPONENT
I, Edward H Kaplan , MD, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____
Edward H Kaplan , MD Date
*If notary is required
SUBSCRIBED AND SWORN TO BEFORE ME THIS
_____ DAY OF _____, 20___.

_____
NOTARY PUBLIC

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

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